

### **REMARKS/ARGUMENTS**

In the September 21, 2004 Office Action, claims 1 - 20 were rejected. After entry of the foregoing amendments, claims 1-20 (20 total claims; 4 independent claims) remain pending in the application. Reconsideration of the application is respectfully requested in view of the above amendments and the following remarks.

#### **Rejections Under 35 U.S.C. § 102**

Claims 1-3, 6-11, 14-17, 19 and 20 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,464,718 to Miller et al. Applicant respectfully traverses this rejection.

The Office Action states that “Miller discloses a balloon having a flexible wall, proximal and distal cones (FIGS. 5-7), proximal and distal ends adapted for being mounted on a catheter, an intermediate body configured to receive a stent (22) thereon, said stent having a proximal end and a distal end, at least one circumferential groove formed on the balloon wall between one of the proximal end and the distal end of the stent (Column 5 line 37-Column 6 line 11) and the respective proximal and distal cone for mechanically disengaging the respective cone from the intermediate body allowing each to move differently in a radial direction (Column 4 lines 31-46) wherein said at least one circumferential groove is present when the balloon is in an inflated and deflated state. Miller also discloses creating dams by inflating the proximal and distal cones and thus retaining the stent on the balloon (Column 4 lines 41-46). Miller also discloses that the groove is formed before the stent is mounted on the balloon (Column 6, lines 37-47).”

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The balloon 10 disclosed in the present application includes proximal and distal circumferential grooves 15, 10, surrounding the balloon 10 adjacent the transitions between intermediate body 12 and distal and distal cones 25, 30. (paragraph 12). The common definition for groove is “a long narrow channel or depression” (Marriam Webster’s Collegiate Dictionary, Tenth Edition). The application discloses example configurations of the grooves, including:

circumferential groove 15 that is substantially U-shaped; circumferential groove 20 that is flat-bottomed or rectangular shaped; circumferential groove 215 that is a substantially U-shaped with unequal distal and proximal diameters; and circumferential groove 315 that is substantially W-shaped. All of these disclosed circumferential grooves are in agreement with the common meaning of the word "groove".

In contrast, nowhere in Miller is a balloon disclosed having "at least one circumferential groove formed on the balloon wall between one of the proximal end and distal end of the stent and the respective proximal and distal cone", as required by claim 1. Miller discloses a balloon catheter for stent delivery that "has a cylindrical working portion with an inflatable diameter located between a pair of conical end portions, and a pair of proximal and distal legs affixed to the shaft. The balloon in its deflated shape preferably has several pleats that are wrapped around the shaft." (Miller, col. 3 line 66 to col. 4 line 3). "The balloon initially is in a deflated state and has a deflated profile shape, as specifically illustrated in FIG.5, having a central bed portion with a deflated bed diameter being flanked by a pair of proximal and distal shoulders or puffs defining deflated shoulders or puffs diameters that are larger than the deflated bed." (Miller, col. 4 lines 12-16). None of the configurations in Miller have a circumferential groove as defined in the present application.

The present application points out that one of the advantages of the circumferential grooves 15, 20 in the balloon 10 is to "create a partial mechanical disengagement between the balloon body 12 and cones 25, 30. The partial disengagement permits adjacent body 12 and cones 25, 30 to move differently in the radial direction, comparable to the way a rolling diaphragm works in the axial direction." (paragraph 18). Claim 1 requires this important feature by claiming that the at least one circumferential groove formed on the balloon is for "mechanically disengaging the respective cone from the intermediate body allowing each to move differently in a radial direction". Looking also at the figures of the present application, it is clear that the outer surface of the balloon body 12 is distinct and separate from the outer surface of the cones 25, 30, and they are separated by the circumferential grooves 15, 20.

In contrast, Miller describes a balloon with a continuous surface (Miller, Figures 7-10), stating that when the balloon is in its fully inflated profile shape, the stent bed shape disappears and the balloon shape changes or morphs into a different profile shape when inflated at full

inflation pressure. (Miller, col. 4 lines 47-54, Figure 7). In Miller, the cylindrical working portion (balloon body) is not distinct and separate from the conical end portions (cones), and they are not separated by circumferential grooves.

Claim 1 also requires that the "at least one circumferential groove is present when the balloon is in an inflated state and a deflated state" (see also FIGs. 1 for inflated state and FIG. 6 for deflated state). Miller does not have a circumferential groove that is present when the balloon is in an inflated state, stating that when the balloon is inflated, the stent bed shape disappears. (Miller, col. 4 lines 47-54, Figure 7). In addition, in the deflated state, the Miller balloon has shoulders or puffs, which are not the same as the claimed circumferential groove.

For at least the reasons given above, Miller fails to teach each and every element of claim 1, namely "at least one circumferential groove formed on the balloon wall between one of the proximal end and distal end of the stent and the respective proximal and distal cone for mechanically disengaging the respective cone from the intermediate body allowing each to move differently in a radial direction wherein said at least one circumferential groove is present when the balloon is in an inflated state and a deflated state."

Accordingly, neither independent claim 1 nor dependent claims 2-3, 19 is anticipated by Miller. By similar reasons, independent claim 6 along with dependent claims 7-9, independent claim 10 along with dependent claims 11, 14, and independent claim 15 along with dependent claims 16-17, 20, are not anticipated by Miller. The Applicant respectfully requests withdrawal of this rejection.

### **Rejections Under 35 U.S.C. § 103**

Claims 4, 5, 12, 13 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. '718 in view of U.S. Patent No. 6,254,608 to Solar. Applicant respectfully traverses this rejection.

As discussed above, independent claims 1, 10 and 15, upon which the rejected claims 4, 5, 12, 13 and 18 depend, are allowable over the prior art. Accordingly, reconsideration and withdrawal of the rejection of claims 4, 5 (dependent on independent claim 1), claims 12, 13 (dependent on independent claim 10), and claim 18 (dependent on independent claim 15), under 35 U.S.C. 103(a) is respectfully requested.

**CONCLUSION**

In view of Applicant's amendments and remarks, it is respectfully submitted that Examiner's rejections under 35 USC § 102 and 103, have been overcome. Accordingly, Applicants respectfully submit that the application, as amended, is now in condition for allowance, and such allowance is therefore earnestly requested. Should the Examiner have any questions or wish to further discuss this application, Applicants request that the Examiner contact the undersigned attorney at (707) 543-0221.

If for some reason Applicants have not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent abandonment on this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 01-2525 for any fee which may be due.

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Respectfully submitted,

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